REMARKS

This application has been carefully considered in light of the Final Office Action of February 12, 2003. As a result, claim 1 has been amended so as to further define the term "prolonging" as it relates to the local effect of a pharmaceutically or cosmetically active substance. In the preamble of the claim, it is noted that the prolongation is with respect to oil-in-water emulsions used to create topical creams or lotions such that when a galactolipid material is used as the emulsifier, there is a prolongation of the local effect of the pharmaceutically or cosmetically active substance. It is respectfully submitted that no specific time or duration of the prolongation is necessary in order to define patentability.

Claims 1-13 remain within the application for prosecution. Claims 1-13 have been rejected under 35 U.S.C. § 103(a) as being obvious and therefore unpatentable over US Patent 6,068,860 when considered in view of WO 95/20943. Claim 12 has been rejected under 35 U.S.C. § 103(a) over the primary two references when further considered in view of the teachings of the reference to US Patent 4,444,755.

The basis of the rejection of the claims for obviousness is that the Examiner believes that US Patent 6,068,860 inherently teaches compositions which exhibit a prolonged effect for a pharmaceutically or cosmetically active substance. However, the Examiner acknowledges that the reference does not explicitly describe such a prolonging effect, but suggests that one of ordinary skill in the art would recognize a prolonged effect as an implicit teaching of the reference. The Examiner directly refers to what is stated at column 3, at lines 45-48 of the reference. What is referenced at this portion of the reference is that, within the teachings of the patent, in order to provide an effective topical treatment of recurrent herpes infections, the first problem which must be solved is to bring a sufficient amount of active substance to penetrate the stratum corneum rapidly and the second problem is to accumulate the active substance at the proper site.

Applicants' respectfully disagree with the Examiner's statement that:

"the prolonged effect is inherent since the composition allows for the active agent to not only penetrate the skin but accumulation of the drug at high concentration at a given site

provides for a prolonged local effect since a continued dose of the active is being supplied at the site."

It is respectfully submitted that rapid penetration of an active substance and targeting of the substance at a specific site does not teach or suggest that a local effect of the active substance is somehow prolonged. If anything, the reference teaches away from the concept of prolonging a local effect of the active substance as the active substance rapidly penetrates the outer layer of skin to which the active substance is applied.

By way of example, the Examiner's attention is directed to the biological test disclosed at column 10 of the reference. The pig skin experiment disclosed in US Patent 6,068,860 shows the distribution of an active compound, foscarnet, in the different layers of the skin after three hours after application of three different formulations: A, which is a galactolipid based gel; B, which is a phospholipid based formulation and C which is a conventional cream. The results show that after three hours A and C have slightly lower concentration in the stratum corneum than B (P=0.03 according to an ANOVA test), implying a faster transport through the outer layers of the skin for these two

formulations. However, the differences are very small, 2.1% for both A and C. There is no significant difference between A and C. For a person skilled in the art, the conclusion drawn from this, if any, would be that B penetrates the outer skin layers less rapidly than A and C and hence should be more suited choice for a prolonged effect system. On the other hand, nothing in this study implies that A should be suitable for such a system.

In the instance application, test examples are provided which reflect the prolonged moisturizing and smoothing effect which is achieved utilizing compositions of the present invention. It is noted that these tests reflect a prolonged moisturizing and smoothing effect on the surface of the subjects' skin over a prolonged period of time. It is respectfully submitted that one of ordinary skill in the art would not look to the teachings of US Patent 6,068,860 to obtain such a prolonged effect as the reference teaches a rapid passing of the active substance through the stratum corneum and thus drawing the active substance away from the surface.

In view of the foregoing, it is believed that a person of ordinary skill in the art would be hesitant to draw a conclusion

regarding the suitability to use any of the formulations disclosed in US Patent 6,068,860 for creating compositons which prolong a local effect of an active substance as the reference teaches rapid penetration of a substance. The reference does not suggest that the compositions therein would have an effect to prolong the local effect of an active substance, especially on outer skin layers. In addition, one of ordinary skill in the art would be aware that galactolipid/water gels behave significantly different from oil-in-water emulsions.

The Examiner has also stated that with respect to the secondary reference, in the absence of showing an unexpected result, it is the Examiner's position that the prolonged effect is inherent since the composition of the present invention and that of the prior art secondary reference are similar and therefore would exhibit similar characteristics. However, it should be noted that the present application specifically states at page 4, beginning at line 5, that it was surprisingly found that a topical cream or lotion of an oil-in-water emulsion type, in which a galactolipid material is used as the emulsifier, and into which a variety of pharmaceutical or cosmetic compounds are

incorporated, gives a sustained local effect of the incorporated compounds when the compounds are applied to the skin. This is certainly an unexpected result as stated in the application. Further, as stated beginning at line 16 of page 3 of the present application, topical creams of the oil-in-water emulsion type had not previously been reported as having any potential sustained release properties. Although oil-in-water emulsions are taught as carriers in the secondary reference to WO 95/20943, there is no teaching nor suggestion that the local effect of an active substance can be prolonged by using an oil-in-water emulsion with a galactolipid material as an emulsifier in a topically applied composition.

In addition to the foregoing, it is respectfully submitted that one of ordinary skill in the art would not look to modify the teachings of the primary reference to Carlsson et al., US Patent 6,068,860, utilizing the teachings of WO 95/20943 because there is nothing in either reference which would suggest that the desired quick penetrating and targeting of an active substance would be enhanced utilizing any of the teachings of the secondary reference. It would be improper to modify the compositions in

the primary reference without regard to the stated purpose such compositions were developed to provide. Also, the primary reference discloses a carrier which is a gel and does not suggest an oil-in-water emulsion as used by the secondary reference. The Examiner has further stated that the primary reference teaches a cream and the claims of the instant invention recite a topical cream or lotion. However, the present claims are directed to a topical cream or lotion which is formed utilizing an oil-in-water carrier and not a gel carrier as is taught in the primary reference.

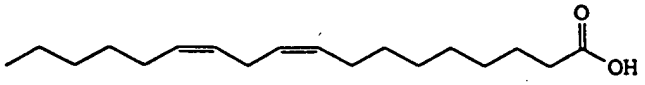
In view of the foregoing, reconsideration of the grounds for rejection of claims 1-13 for obviousness is respectfully requested and favorable consideration of the claims solicited.

As it is respectfully submitted that claims 1-13 are distinguishable over the primary and secondary reference, no further discussion is required with respect to the additional rejection of claim 12 over a further combination of the primary and second reference with a third reference to Horrobin, US Patent 4,444,755. However, as the Examiner has further stated that the primrose oil used in the WO publication inherently

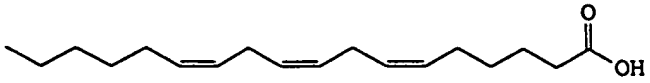
contains a specific fatty acid, it is believed that a comment should be made to correct a misunderstanding.

It is respectfully submitted that there are differences between the fatty acids mentioned in the WO publication and the additional reference to Horrobin.

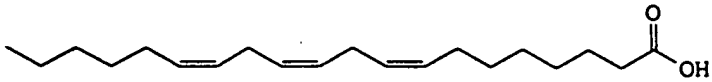
13-hydroxylinoleic acid is not present in evening primrose oil, and is not mentioned in any of the prior art documents. For clarity we enclose the structures of linoleic, gammalinolenic acid, dihomogammalinolenic acid and 13-hydroxylinoleic acid (the three former being present in evening primrose oil).



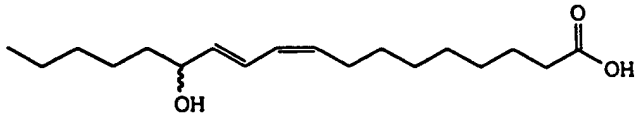
Linoleic acid (9,12-18:2)



Gammalinolenic acid (6,9,12-18:3)



Dihomogammalinolenic acid (8,11,13-20:3)*



13-Hydroxylinoleic acid (13-OH-9,11-18:2)

*Note that in US 4,444,755 dihomogammalinolenic acid is incorrectly denoted as 5,8,11-eicosatrienoic acid.

In view of the foregoing, reconsideration of the rejection of claim 12 for obviousness is also respectfully requested.

An earnest effort has been made to place this application in condition for allowance which action is solicited. Should the Examiner have any further questions regarding the allowability of the application, it would be appreciated if the Examiner would contact the undersigned attorney-of-record at the telephone number shown below.

Respectfully submitted,

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